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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,861	JACOBS ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *012604*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the first line of the claim, "the step of drying" lacks positive antecedent basis since no such step has been previously recited.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

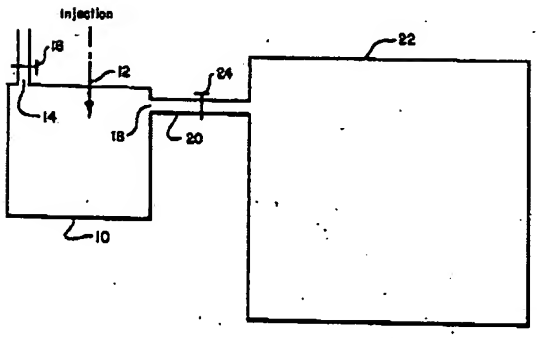
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7, 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al. (U.S. Patent No. 4,744,951) in view of Forstrom et al. (U.S. Patent No. 4,169,124), or alternatively, over Moore et al. in view of Cummings et al..

As to claims 1-7, 9, and 10, Cummings et al. teaches a method of sterilizing wherein an article is placed into a sterilizing chamber **22**, the chamber is evacuated (dried), a dilute



(0.05-5%) aqueous solution of H_2O_2 is introduced into an enclosure **10** having a diffusion restriction **20** in fluid communication with the chamber **22** and vaporized. Thereafter, water vapor is drawn off through port **14** to increase the ratio of H_2O_2 to water. All of the preceding steps occur with valve **24** closed. Valve **24** is then opened and the H_2O_2 is furnished to the article within evacuated chamber **22** for sterilization. See Figure and col.3, lines 29-55. Cummings et al. discloses that "conditions within the chamber" are controlled to cause the preferential vaporization of water from the solution. As shown in the Examples, the pressure and temperature are controlled to achieve this preferential vaporization. Cummings et al discloses a preferred final concentration of hydrogen peroxide (50-80%), which encompasses the claimed ratios. Cummings et al. fails to teach

drawing the water vapor from the chamber **22** containing the article since the liquid hydrogen peroxide is not vaporized in the sterilization chamber **22**, only in the vaporization chamber **10**.

Forstrom et al. discloses a method of hydrogen peroxide sterilization wherein a small amount of dilute hydrogen peroxide **12** is introduced into a chamber **1**, along with an article **9,10** to be sterilized, and the hydrogen peroxide then vaporized to sterilize the article. Vaporization occurs when the chamber is evacuated through diffusion restriction **5**. See col.4, lines 4-25; Figure 1 and 2.

It would have been obvious to one of ordinary skill in the art to introduce the liquid hydrogen peroxide directly into the sterilization chamber of Cummings et al. (or simply to omit valve **24**) and to vaporize the hydrogen peroxide there, as Forstrom et al. evidences that it is possible to furnish hydrogen peroxide to an article by either (a) vaporizing the hydrogen peroxide *in situ*, or (b) vaporizing the hydrogen peroxide in a separate location and injecting the gaseous peroxide into the sterilization chamber. See col.3, lines 31-42. As the two methods of furnishing the hydrogen peroxide are functional equivalents they would have been easily substituted.

Alternatively, one would have found it obvious to preferentially remove the water vapor from the generated vapor of Forstrom et al. since Cummings et al. teaches that doing so yields a higher peroxide concentration and thus, an improved sterilization efficacy. See Examples 3-5.

With respect to claims 11-19, it is known to those in the art that vaporization of a component of a solution occurs when the vapor pressure of the component exceeds that its surroundings. This vaporization can be achieved by increasing the vapor pressure of the component through two means: heating the solution to increase the vapor pressure thereof or

lowering the surrounding pressure. (See for example Forstrom et al. which teaches imposing a vacuum on the chamber in combination with heat to promote vaporization of the solution.) Thus, it would have been obvious to control both of these parameters in any desired combination or order in order to control vaporization of the water from the solution and to achieve the desired final concentration of hydrogen peroxide, as taught by Cummings et al..

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al. and Forstrom et al. as applied to claim 18 above, and further in view of Spencer et al. (U.S. Patent No. 5,656,238).

Cummings et al. discloses pumping a portion of the atmosphere out of the chamber in order to dry the chamber but does not teach applying energy thereto. Spencer et al. teaches that the application of a plasma during an initial evacuation step promotes drying of the chamber and allows a desired pressure to be attained more quickly than without the plasma. See Abstract. For these reasons, it would have been obvious to apply energy during the drying step of the combination *supra*.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of prior U.S. Patent No. 6,656,424. This is a double patenting rejection.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,325,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims fully encompass the claims of the instant application.

12. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 5 of U.S. Patent No. 6,627,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims fully encompass the instant claims.

Information Disclosure Statement

13. The information disclosure statement filed 26 January 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the

content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the German document, DT 2623917 has not been considered.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Addy et al. (EP 799621) reads on at least instant claims 1, 2, 4, 5, 7, 9-13, 16, and 17. However, Addy et al was published 8 October 1997. The present application claims continuity to 08/628965, which was filed 4 April 1996. Serial no. 08/628965 is the parent of 09/216381 which is the U.S. equivalent of EP 799621.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane
Primary Examiner
Art Unit 1744

elm
24 October 2005